IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc.)))
Plaintiff,))
vs.) Case No. 04-12457 PBS
Arthrex, Inc.,)
Defendant.))

PEARSALLS LIMITED'S ANSWER AND COUNTERCLAIM IN RESPONSE TO DEPUY MITEK, INC.'S AMENDED COMPLAINT

Defendant Pearsalls Limited ("Pearsalls") responds to the Amended Complaint filed by Plaintiff DePuy Mitek, Inc. ("DePuy Mitek") as follows:

Parties, Jurisdiction and Venue

- 1. The Complaint purports to bring an action for patent infringement. The remaining allegations of paragraph 1 assert legal conclusions that do not require a response.
 - 2. Admitted.
 - 3. Admitted.
 - 4. Admitted.

Answer to Depuy Mitek's Claim for Relief

5. Pearsalls admits that U.S. Patent No. 5,314,446 ("the '446 patent") entitled "Sterilized Heterogeneous Braids" is attached as Exhibit A to the Complaint, and that it issued on May 24, 1994 listing Ethicon as the assignee on the cover page.

DSMDB.1992134.1

Pearsalls has no knowledge or information sufficient to confirm whether Ethicon, Inc. assigned the '446 patent to DePuy Mitek and therefore denies the same. Pearsalls denies that the patent was duly and legally issued by the U.S. Patent and Trademark Office.

- Pearsalls admits that Arthrex sells sutures under the trade name FiberWire™ in the United States, including within this judicial district, but denies each and every other allegation contained in paragraph 6 of the Amended Complaint.
- Pearsalls denies each and every allegation contained in paragraph 7 of the Amended Complaint.
- Pearsalls admits that it was involved in the design, development and 8. commercialization of FiberWire™ and TigerWire® sutures and that at least some of those products would be sold in the United States. Pearsalls denies the remaining allegations of paragraph 8 of the Amended Complaint.
- Pearsalls has insufficient information to admit or deny the allegations 9. of the first sentence of paragraph 9 and therefore denies those allegations. Pearsalls denies the remaining allegations of paragraph 9.
- 10. Pearsalls admits the allegations of paragraph 10 of the Amended Complaint.
- 11. Pearsalls denies each and every allegation contained in paragraph 11 of the Amended Complaint.

FURTHER ANSWERING, Pearsalls presents the following affirmative defenses:

AFFIRMATIVE DEFENSES

- 12. The Court lacks personal jurisdiction over Pearsalls since Pearsalls does not reside within this judicial district and DePuy Mitek has failed to allege that Pearsalls engages in business activity within this judicial district sufficient to vest this Court with personal jurisdiction over Pearsalls.
- 13. Service was insufficient because, upon information and belief, service of process was not performed in compliance with Rule 4(f) of the Federal Rules of Civil Procedure.
 - 14. The '446 patent is invalid under 35 U.S.C. § 102.
 - The '446 patent is invalid under 35 U.S.C. § 103.
 - The '446 patent is invalid under 35 U.S.C. § 112.
- 17. Pearsalls does not now infringe and has not infringed the '446 patent either literally or under the doctrine of equivalents.
- 18. Pearsalls does not now induce and has not induced others to infringe the '446 patent either literally or under the doctrine of equivalents.
- 19. Upon information and belief, the '446 patent is unenforceable due to inequitable conduct committed before the U.S. Patent and Trademark Office ("the Patent Office") during prosecution of the application which eventually issued as the '446 patent for the following reasons, among others.
- 20. During prosecution of U.S. Application No. 838,511 ("the '511 application"), which eventually issued as the '446 patent, the applicants and their attorneys mischaracterized and misrepresented the disclosure of U.S. Patent No. 5,147,400 to Kaplan et al. ("Kaplan") in distinguishing Kaplan from the claims of the '511 application. For example, in response to rejections on anticipation and obviousness

grounds under 35 U.S.C. §§ 102, 103, on August 4, 1993, the applicants and their attorneys falsely represented that the sheath yarn component of Kaplan always contains at least in part, a bio-absorbable portion and that Kaplan teaches away from a combination of non-bio-absorbable yarns. Kaplan, however, does not always contain a bio-absorbable portion and discloses a combination of non-bio-absorbable yarns.

- 21. During the prosecution of the '511 application, applicants and their attorneys responded to a rejection based on U.K. Patent Application No. 2,218,312A to Burgess ("Burgess") by stating in a response, filed on August 6, 1992, that the use of a high tensile polythene thread in a braided construction would have poor qualities for a suture and that a designer using such materials for a suture would inevitably design an unacceptable suture. If applicants and their attorneys believed that high tensile polythene was included within their claimed invention, then they could not have truthfully made these statements and representations to the examiner.
- 22. The applicants and their attorneys acted with intent to deceive the Patent Office since they knew or should have known that their statements were false and misleading and that the Patent Office would rely on such statements in reconsidering the rejections in light of Kaplan and Burgess. In fact, following the applicants' and their attorneys' misrepresentations and mischaracterizations of Kaplan and Burgess, the '511 application was allowed and eventually issued as the '446 patent.
- 23. DePuy Mitek, by virtue of its efforts to obtain, enforce and use the '446 patent, knowing said patent to be invalid, uninfringed, and unenforceable, have misused said patent, whereby DePuy Mitek is precluded from enforcing the same against Pearsalls.

COUNTERCLAIM

- Pearsalls is a private limited company organized under the laws of 1. the United Kingdom with a principal place of business at Tancred Street, Taunton, Somerset TA1 1RY.
- DePuy Mitek is a corporation organized under the laws of the State of Massachusetts, with its corporate headquarters and principal place of business at 249 Vanderbilt Avenue, Norwood, Massachusetts 02062.
- Pearsalls repeats and realleges and incorporates herein by reference, 3. paragraphs 12-23 of its Affirmative Defenses.
- This is a claim arising under the Patent Laws of the United States, Title 35, United States Code, for a declaratory judgment under 28 U.S.C. §§ 2201 and 2202. The jurisdiction of this Court is founded upon 28 U.S.C. §§ 1338(a), 2201 and 2202.
- DePuy Mitek alleges that it is the owner of the '446 patent. There exists an actual controversy between Pearsalls and DePuy Mitek with respect to the validity, enforceability, scope and infringement of the '446 patent.
- The '446 patent is not infringed, and further is invalid and 6. unenforceable at least for the reasons set forth in paragraphs 14-23 of Pearsalls' Affirmative Defenses.
- Pearsalls seeks a declaration by the Court that the '446 patent is not 7. infringed, either directly or by inducement, by Pearsalls, that the '446 patent is invalid and unenforceable, and that DePuy Mitek, knowing that the '446 patent is invalid, not infringed by Pearsalls and unenforceable, while asserting the patent against Pearsalls, has committed patent misuse.

8. DePuy Mitek's conduct renders this an exceptional case within the provisions of 35 U.S.C. § 285, and Pearsalls is accordingly entitled to an award of attorneys' fees.

WHEREFORE, Pearsalls prays for judgment against DePuy Mitek as follows:

- A. That the Court deny all relief to DePuy Mitek, and that the Amended Complaint be dismissed with prejudice;
- B. That the Court decree, adjudge and declare that the '446 patent is invalid, not infringed by Pearsalls, directly or through inducement, and unenforceable and that DePuy Mitek has committed patent misuse by knowingly asserting an invalid and unenforceable patent against Pearsalls, with knowledge that Pearsalls does not infringe said patent;
- C. That the Court find this an exceptional case and award reasonable attorney fees to Pearsalls under 35 U.S.C. § 285;
 - D. That the Court award Pearsalls its costs, and expenses; and
 - E. That the Court grant such further relief as it deems just and proper.

JURY DEMAND

Pearsalls demands a trial by jury on all issues triable to a jury with respect to its counterclaim.

Dated: October 14, 2005 Respectfully submitted,

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Counsel for Defendants Arthrex, Inc. and Pearsalls Limited

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Pearsalls

Limited's Answer and Counterclaim in Response to DePuy Mitek, Inc.'s Amended

Complaint was electronically filed with the Court and served via the Court's email

notification service on October 14, 2005, upon the following counsel for DePuy Mitek,

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